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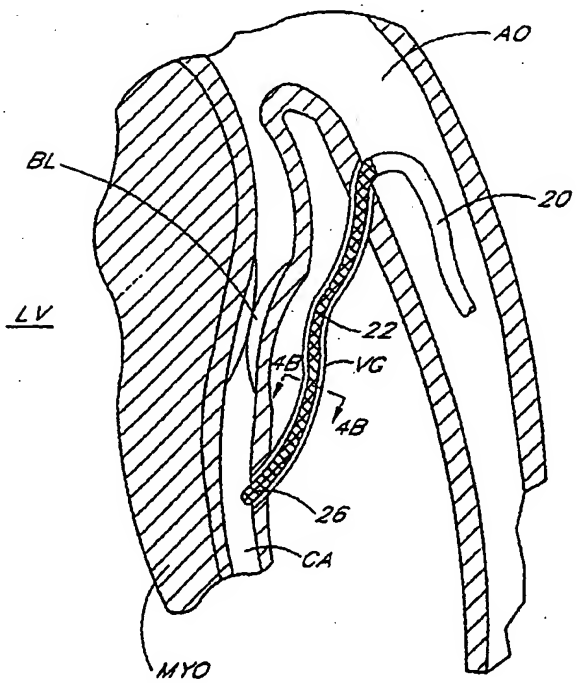
(54) Title: INNER LINER FOR A VASCULAR GRAFT BYPASS




(57) Abstract: Improved methods of treatment of diseased or occluded vascular grafts in patients having undergone coronary artery bypass or other bypass surgery are disclosed. Deployment of a conduit in the myocardium at a site distal to the site of attachment of the coronary artery bypass graft allows oxygenated blood to flow from a chamber in the heart directly into the coronary artery, bypassing blockages in the coronary artery and the graft originally used to bypass the coronary artery. To ensure proper positioning, the conduit is delivered through the graft to the myocardium. A new lining for the existing vein graft and methods of delivery are also disclosed.

WO 01/10349 A1

# INNER LINER FOR A VASCULAR GRAFT BYPASS

## Background of the Invention

### Field of the Invention

This invention relates to an improved treatment of diseased or occluded vascular grafts in patients having undergone coronary artery bypass surgery.

### Description of the Related Art

Coronary artery disease is a major problem in the U.S. and throughout the world. Coronary arteries as well as other blood vessels frequently become clogged with plaque, which at the very least impairs the efficiency of the heart's pumping action, and can lead to heart attack and death. In some cases, these arteries can be unblocked through non-invasive techniques such as balloon angioplasty. In more difficult cases, a bypass of the blocked vessel is necessary.

In a bypass operation, one or more venous segments are inserted between the aorta and the coronary artery. The inserted venous segments or transplants act as a bypass of the blocked portion of the coronary artery and thus provide for a free or unobstructed flow of blood to the heart. More than 500,000 bypass procedures are performed in the U.S. every year.

Such coronary artery bypass surgery, however, is a very intrusive procedure that is expensive, time-consuming and traumatic to the patient. The operation requires an incision through the patient's sternum (sternotomy), and that the patient be placed on a bypass pump so that the heart can be operated on while not beating. A saphenous vein graft is harvested from the patient's leg, another highly invasive procedure, and a delicate surgical procedure is required to piece the bypass graft to the coronary artery (anastomosis). Hospital stays subsequent to the surgery and convalescence are prolonged.

Over time, the vein graft itself may become diseased, stenosed, or occluded, similar to the original bypassed vessel. Old, diffusely diseased saphenous vein grafts are considered contraindications for angioplasty and atherectomy, severely limiting the options for minimally invasive treatment. Some diseased or occluded saphenous vein grafts are associated with acute ischemic syndromes, however, necessitating some form of intervention.

Thus, there is a need for an improved treatment of diseased or occluded grafts in patients having had coronary bypass surgery.

## Summary of the Invention

The preferred embodiments of the present invention address the need in the previous technology by providing a bypass system that restores the flow of oxygenated blood through the body. In a preferred embodiment, there is provided a method for bypassing an existing coronary artery bypass graft in a patient. A hollow conduit is inserted in the patient's myocardium at a location distal to the site of attachment of the graft, such that the conduit allows oxygenated blood to flow from the patient's heart directly into the coronary artery. The conduit is preferably delivered to the myocardium through the coronary artery bypass graft, to ensure that the conduit is positioned in the myocardium at a site that is distal to both the blockage in the coronary artery, and the site of attachment of the graft to the coronary artery. Locating the proper site, for example, through the left ventricle of the heart is very difficult. Thus, delivery of the conduit through the graft simultaneously solves both the problem of therapy and the problem of locating the proper site for insertion of the conduit in bypass patients.

The methods disclosed herein are preferably performed percutaneously, but other minimally invasive methods, and open-chest methods, can also be used. Prior to insertion into the patient, the conduit is preferably mounted on the distal end of a delivery catheter. The catheter is then inserted into the patient's vasculature, into the aorta, and then into the bypass graft for delivery into the myocardium.

Another embodiment of the invention includes a method for improving the patency of a coronary artery or other arterial or venous bypass graft. A lining is inserted in the hollow interior of the graft and preferably permanently attached to the graft. The lining can be made of various biocompatible materials, but a section of vein from the patient is preferred. The lining can be mounted on an inflatable balloon catheter, such as those used in angioplasty. The distal end of the catheter is delivered to the interior of the graft, and the balloon is inflated to expand the lumen of the graft and the lining. If desired, a delivery catheter can be used to deliver the catheter

bearing the lining to the site of the graft. This method improves the "proximal flow" through the existing graft.

The methods disclosed herein for bypassing an existing graft and for improving the patency of an existing bypass graft can be used in combination, or in the alternative.

## Brief Description of the Drawings

FIGURE 1 is a cross-sectional view of a human heart, showing a saphenous vein graft used to bypass a blockage in the coronary artery.

FIGURE 2 is a cross-sectional view of a conduit placed in the myocardium to provide for the flow of oxygenated blood directly from the left ventricle in the heart into the coronary artery, bypassing the blockages in the coronary artery and the saphenous vein graft.

FIGURES 3A-C are enlarged views illustrating the delivery of the conduit through the saphenous vein graft and into the myocardium.

FIGURES 4A-E are enlarged views illustrating the delivery of a new vein lining into an existing vein graft used to bypass a blockage in the coronary artery.

## Detailed Description of the Preferred Embodiment

As is well known, the coronary artery branches off the aorta and is positioned along the external surface of the heart wall. Oxygenated blood flows from the heart to the aorta, and on to the rest of the body, some of the blood flowing into the coronary artery. In some individuals, plaque builds up within the coronary artery, blocking the free flow of blood and causing complications ranging from mild angina to heart attack and death.

In order to restore the flow of oxygenated blood through the coronary artery, bypass surgery is performed. One or more venous segments are used to join the aorta and a site in the coronary artery distal to the blockage. The inserted vascular segments act to bypass the blocked portion of the coronary artery and thus provide for a free or unobstructed flow of oxygenated blood from the heart. To perform the bypass, an incision is made through the patient's sternum (sternotomy), and the patient is placed on a bypass pump so that the heart and surrounding vessels can be operated on while not beating. Typically, a saphenous vein graft is harvested from the patient's leg, and

the bypass graft is anastomosed to the aorta and to the coronary artery. It should be understood, however, that other arterial or venous segments may be used to perform the bypass and that other blocked vessels may be bypassed. The term "vascular graft" as used herein refers to any such venous or arterial segment used in any bypass procedure.

FIGURE 1 illustrates a human heart having a saphenous vein graft VG attached to the aorta AO and to the coronary artery CA at a site distal to the blockage BL in the coronary artery CA. As noted above, over time, the vein graft VG itself may become diseased, stenosed, or occluded, and intervention is necessary to once again restore the flow of oxygenated blood through the coronary artery CA.

FIGURE 2 illustrates means for bypassing the blockage BL in the coronary artery, as well as in the vein graft VG. A conduit 10 is positioned in the heart wall or myocardium MYO. Although the bypass described herein is from the left ventricle of the heart to the coronary artery, it should be understood that this is merely exemplary. The principles of the present invention are not limited to left ventricular conduits, and include conduits for communicating bodily fluids from any space within a patient to another space within a patient, including any mammal. Furthermore, such fluid communication through the conduits is not limited to any particular direction of flow and can be antegrade or retrograde with respect to the normal flow of fluid. Moreover, the conduits may communicate between a bodily space and a vessel or from one vessel to another vessel (such as an artery to a vein or vice versa). Moreover, the conduits can reside in a single bodily space so as to communicate fluids from one portion of the space to another. For example, the conduits can be used to achieve a bypass within a single vessel, such as communicating blood from a proximal portion of an occluded coronary artery to a more distal portion of that same coronary artery.

In addition, the conduits and related methods can preferably traverse various intermediate destinations and are not limited to any particular flow sequence. For example, in one preferred embodiment of the present invention, the conduit communicates from the left ventricle, through the myocardium, into the pericardial space, and then into the coronary artery. However, other preferred embodiments are

disclosed, including direct transmyocardial communication from a left ventricle, through the myocardium and into the coronary artery. Thus, as emphasized above, the term "transmyocardial" should not be narrowly construed in connection with the preferred fluid communication conduits, and other non-myocardial and even non-cardiac fluid communication are preferred as well. With respect to the walls of the heart (and more specifically the term "heart wall"), the preferred conduits and related methods are capable of fluid communication through all such walls including, without limitation, the pericardium, epicardium, myocardium, endocardium, septum, etc.

The bypass which is achieved with certain preferred embodiments and related methods is not limited to a complete bypass of bodily fluid flow, but can also include a partial bypass which advantageously supplements the normal bodily blood flow. Moreover, the occlusions which are bypassed may be of a partial or complete nature, and therefore the terminology "bypass" or "occlusion" should not be construed to be limited to a complete bypass or a complete occlusion but can include partial bypass and partial occlusion as described.

The preferred conduits and related methods disclosed herein can also provide complete passages or partial passages through bodily tissues. In this regard, the conduits can comprise stents, shunts, or the like, and therefore provide a passageway or opening for bodily fluid such as blood. Moreover, the conduits are not necessarily stented or lined with a device but can comprise mere tunnels or openings formed in the tissues of the patient.

The conduits of the present invention preferably comprise both integral or one-piece conduits as well as plural sections joined together to form a continuous conduit. The present conduits can be deployed in a variety of methods consistent with sound medical practice including vascular or surgical deliveries, including minimally invasive techniques. For example, various preferred embodiments of delivery rods and associated methods may be used. In one embodiment, the delivery rod is solid and trocar-like. It may be rigid or semi-rigid and capable of penetrating the tissues of the patient and thereby form the conduit, in whole or in part, for purposes of fluid communication. In other preferred embodiments, the delivery rods may be hollow so as to form the conduits themselves (e.g., the conduits are preferably self-implanting or

self-inserting) or have a conduit mounted thereon (e.g., the delivery rod is preferably withdrawn leaving the conduit installed). Thus, the preferred conduit device and method for installation is preferably determined by appropriate patient indications in accordance with sound medical practices.

The conduit 10, as illustrated in FIGURE 2, preferably extends from the left ventricle LV of the heart to the coronary artery CA at a site that is distal to the site of the blockage BL. The conduit 10 is preferably made of a biocompatible material such as titanium, titanium alloys, nickel alloys, or a biocompatible polymer. If desired, the conduit 10 can incorporate a valve that allows blood to flow freely from the left ventricle LV to the coronary artery CA but prevents the backflow of blood from the coronary artery 10 to the heart. Further details regarding conduits and conduit delivery systems are described in copending patent applications entitled DELIVERY METHODS FOR LEFT VENTRICULAR. CONDUIT [Attorney Docket No. PERCAR.003CP1], DESIGNS FOR LEFT VENTRICULAR CONDUIT [Attorney Docket No. PERCAR.013A], LEFT VENTRICULAR CONDUIT WITH BLOOD VESSEL GRAFT [Attorney Docket No. PERCAR.005A], VALVE DESIGNS FOR LEFT VENTRICULAR CONDUIT [Attorney Docket No. PERCAR.006A], LEFT VENTRICULAR CONDUITS TO CORONARY ARTERIES AND METHODS FOR CORONARY BYPASS [Attorney Docket No. PERCAR.033CP1], and BLOOD FLOW CONDUIT DELIVERY SYSTEM AND METHOD OF USE [Attorney Docket No. PERCAR.040A], all filed on the same day as the present application, and U.S. Patent Nos. 5,429,144, and No. 5,662,124, the disclosures of which are all hereby incorporated by reference in their entirety.

In order to bypass the blockages in both the coronary artery CA and the vein graft VG, thereby providing for enhanced blood flow in the patient, the conduit 10 must be positioned at a site which is downstream or distal to the blockage BL in the coronary artery CA and the attachment site of the vein graft VG to the coronary artery CA. This allows oxygenated blood to flow directly from the left ventricle LV of the heart into the coronary artery CA and on to the rest of the body without encountering the blockage BL and without having to travel through the blocked vein graft VG. Although some proximal flow may occur through the vein graft, it is advantageous to

place the conduit in a position which completely bypasses the blockage(s). The preferred positioning of the conduit 10 is illustrated in FIGURE 2.

FIGURES 3A-3C depict a preferred method for delivery of the conduit 10 into the myocardium MYO. Although the figures illustrate the delivery of the conduit 10 percutaneously, it should be appreciated that the percutaneous approach is not essential to achieve many objects of the present invention, and therefore, an open-chest or other approach can also be used. In the preferred embodiment illustrated, the conduit 10 is delivered percutaneously, through the aorta AO and through the vein graft VG, thereby ensuring that both the original blockage BL in the coronary artery CA and the vein graft VG itself are bypassed. Other methods of delivery of the conduit 10 through the vein graft VG to a site in the myocardium MYO past both the blockage BL in the coronary artery CA and the site of attachment of the vein graft VG are also contemplated.

The conduit 10 is first mounted on the distal end of a steerable delivery catheter 12 (FIGURE 3A). The catheter 12 is delivered into the patient's vasculature, such as through the femoral artery in the thigh, and through the aorta AO until it reaches the site of attachment of the vein graft VG. The catheter 12 is then delivered through the vein graft VG and into the coronary artery CA. The distal end of the catheter 12 is positioned adjacent the desired insertion point in the myocardium MYO. The conduit 10 is then inserted into the myocardium MYO, such that one end of the conduit 10 is positioned in the left ventricle LV of the heart, and the other end is positioned in the coronary artery CA (FIGURE 3B). Methods of conduit delivery are described in detail in the above-referenced copending application DELIVERY METHODS FOR LEFT VENTRICULAR CONDUIT [Attorney Docket No. PERCAR.003CPI], and in U.S. Patent Nos. 5,429,144 and No. 5,409,019, all of which are hereby incorporated by reference in their entirety. The conduit 10 therefore provides for the shunting of oxygenated blood directly from the left ventricle LV of the heart into the coronary artery CA.

The conduit 10 can include anchoring means such as hooks, barbs, flanges or collars, or can be sutured, stapled or otherwise anchored in place to prevent conduit migration. The position of the conduit can be checked radiographically, and adjusted

if necessary. As illustrated in FIGURE 3C, after the conduit 10 has been properly positioned in the myocardium MYO, the delivery catheter 12 is withdrawn from the patient.

Another embodiment of the present invention is illustrated in FIGURES 4A-D. In this embodiment, an existing vascular graft is provided with a new, biocompatible lining, which allows for the free passage of blood therethrough. The lining can be formed of any biocompatible material, such as various polymers, but is preferably formed from a section of blood vessel, such as a vein, taken from the patient. The section of vein or other blood vessel harvested preferably contains one or more one-way valves, which occur naturally in the veins. In a preferred embodiment, the new vein section used to line the existing graft is obtained from the saphenous vein in the patient. Of course a blood vessel taken from a human or animal donor could also be used. For example, a fetal pig or piglet could be obtained and dissected to remove a section of the pulmonary artery having a pulmonic valve therein, or a section of the aorta having an aortic valve, or any other similar vessel having a naturally occurring valve system.

The vein section harvested is preferably sized so as to be approximately the same length as the original vein graft VG, but other lengths are also contemplated. The natural vein is biocompatible and therefore reduces the occurrence of problems associated with rejection and clotting. In addition, the vein section provides a natural valve system that is already in use throughout the body to prevent the backflow of blood. After the vein section has been harvested, it is mounted on the distal end of a catheter for insertion into the patient, as described below.

Turning now to FIGURE 4A, there is illustrated a steerable delivery catheter 20 having an inner lumen. A vein section 22 obtained as described above is mounted on the distal end of a second catheter 24, which is inserted through the lumen of the delivery catheter 20. The second catheter 24 preferably has an inflatable balloon 26 mounted on its distal end, over which the vein section 22 is concentrically mounted. Inflatable catheters are well known to these of skill in the art, and can be readily obtained from various commercial sources. The delivery catheter 20 and second catheter 24 are preferably delivered together into the patient's vasculature, such as

through the femoral artery in the thigh, and through the aorta AO until they reach the site of attachment of the vein graft VG. The second catheter 24 bearing the vein section 22 is then delivered through the vein graft VG, as illustrated in Figure 4B.

After the new vein section 22, mounted on the distal end of the second catheter 24, is delivered into the vein graft VG, the delivery catheter 20 is withdrawn, as illustrated in FIGURE 4C. The second catheter 24 and new vein section 22 remain in position inside the vein graft VG. The balloon 26 at the distal end of the second catheter 24 is inflated as shown in FIGURE 4D. Expansion of the balloon 26 forces the new vein section 22 against the interior of the existing vein graft VG, expanding the interior lumen in both the existing graft VG and the new vein section 22, opening a new passage for blood to flow through the vein graft VG. The balloon 26 is deflated, and the second catheter 24 is withdrawn from the patient, leaving the existing vein graft VG with a new vein lining, as illustrated in FIGURE 4E.

Preferably, the new vein section 22 is attached to the existing vein graft VG or to the aorta AO at one end and to the coronary artery CA at the other end. The new vein section 22 can be attached by sutures, staples, or other attachment means.

The embodiments illustrated and described above are provided merely as examples of certain preferred embodiments of the present invention. Changes and modifications can be made to the embodiments presented herein by those skilled in the art without departure from the spirit and scope of the invention, as defined by the claims which follow.

WHAT IS CLAIMED IS:

1. A method for bypassing a coronary artery bypass graft in a patient, comprising:

delivering a hollow conduit through the coronary artery bypass graft; and

inserting the conduit in the patient's heart wall at a location distal to a site of attachment of the graft, such that the conduit allows blood to flow from a chamber in the patient's heart directly into the coronary artery.

2. The method of Claim 1, wherein the chamber is the left ventricle.

3. The method of Claim 1, wherein the conduit is mounted on the distal end of a delivery catheter prior to insertion into the patient.

4. The method of Claim 1, further comprising anchoring the conduit into position in the myocardium.

5. The method of Claim 4, wherein said anchoring comprises suturing the conduit into position.

6. The method of Claim 1, further comprising visualizing the position of the conduit in the myocardium radiographically.

7. A method for improving the patency of a coronary artery bypass graft having an interior lumen in a patient, comprising:

inserting a lining into the lumen of said graft.

8. The method of Claim 7, further comprising harvesting a section of a blood vessel from the patient to be used as the lining and inserting the section of blood vessel into the lumen of the graft.

9. The method of Claim 7, further comprising mounting the lining over an inflatable balloon located on a distal end of a catheter, and delivering the distal end of the catheter into the lumen of the graft.

10. The method of Claim 9, further comprising inflating the balloon to expand the lumen of the graft.

11. The method of Claim 9, wherein the catheter is inserted into a lumen in a delivery catheter, and the delivery catheter and the catheter bearing the lining are delivered together into the patient.

12. The method of Claim 7, further comprising permanently attaching the lining to the lumen of the graft.

13. The method of Claim 7, wherein the method is performed percutaneously.

14. A method for improving the patency of a coronary artery bypass graft having a lumen in a patient, comprising:

harvesting a section of vein from the patient, and

delivering the section of vein to the lumen of the graft, such that the section of vein provides a lining in the lumen of the graft.

15. The method of Claim 14, further comprising:

mounting the section of vein over an inflatable balloon located at a distal end of a catheter;

delivering the distal end of the catheter to the lumen of the graft;

inflating the balloon to expand the vein section and graft;

deflating the balloon; and

withdrawing the catheter from the patient.

16. The method of Claim 15, wherein the catheter is first inserted into a lumen in a delivery catheter, and the delivery catheter and the catheter bearing the vein section are delivered together into the patient.

17. The method of Claim 14, further comprising permanently attaching the vein section to the lumen of the graft.

18. The method of Claim 14, wherein the section of vein is sized so as to be approximately the same length as the graft.

19. A device for improving the patency of a coronary artery bypass graft, comprising an inner lining for said graft.

20. The device of Claim 19, wherein the lining is formed from a section of blood vessel.

21. The device of Claim 20, wherein the section of blood vessel is obtained from a human.

22. The device of Claim 20, wherein the blood vessel is a vein.

23. The device of Claim 19, wherein the lining includes a one-way valve.

24. The device of Claim 19, wherein said lining is sized so as to be approximately the same length as the graft.

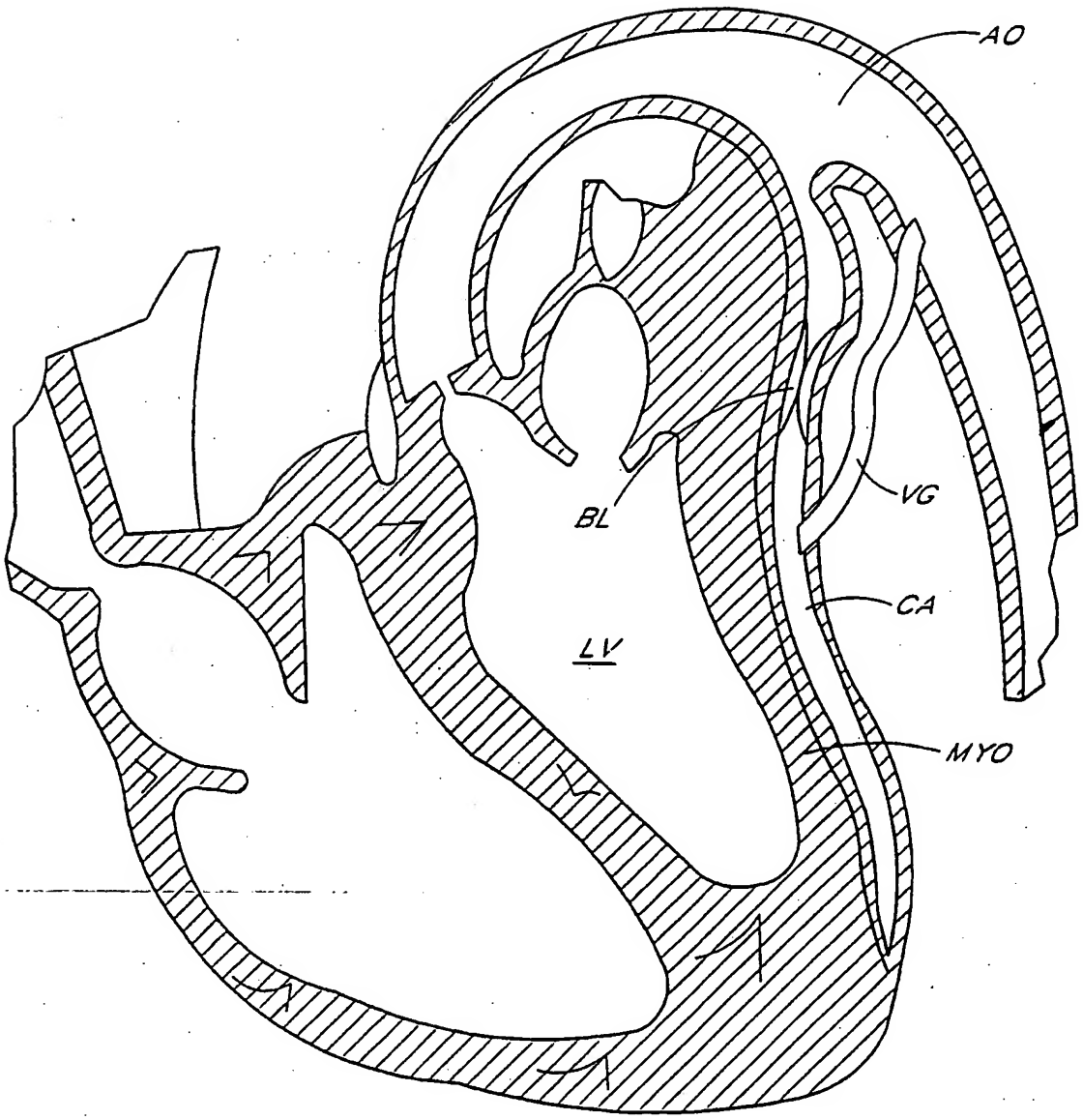



FIG. 1

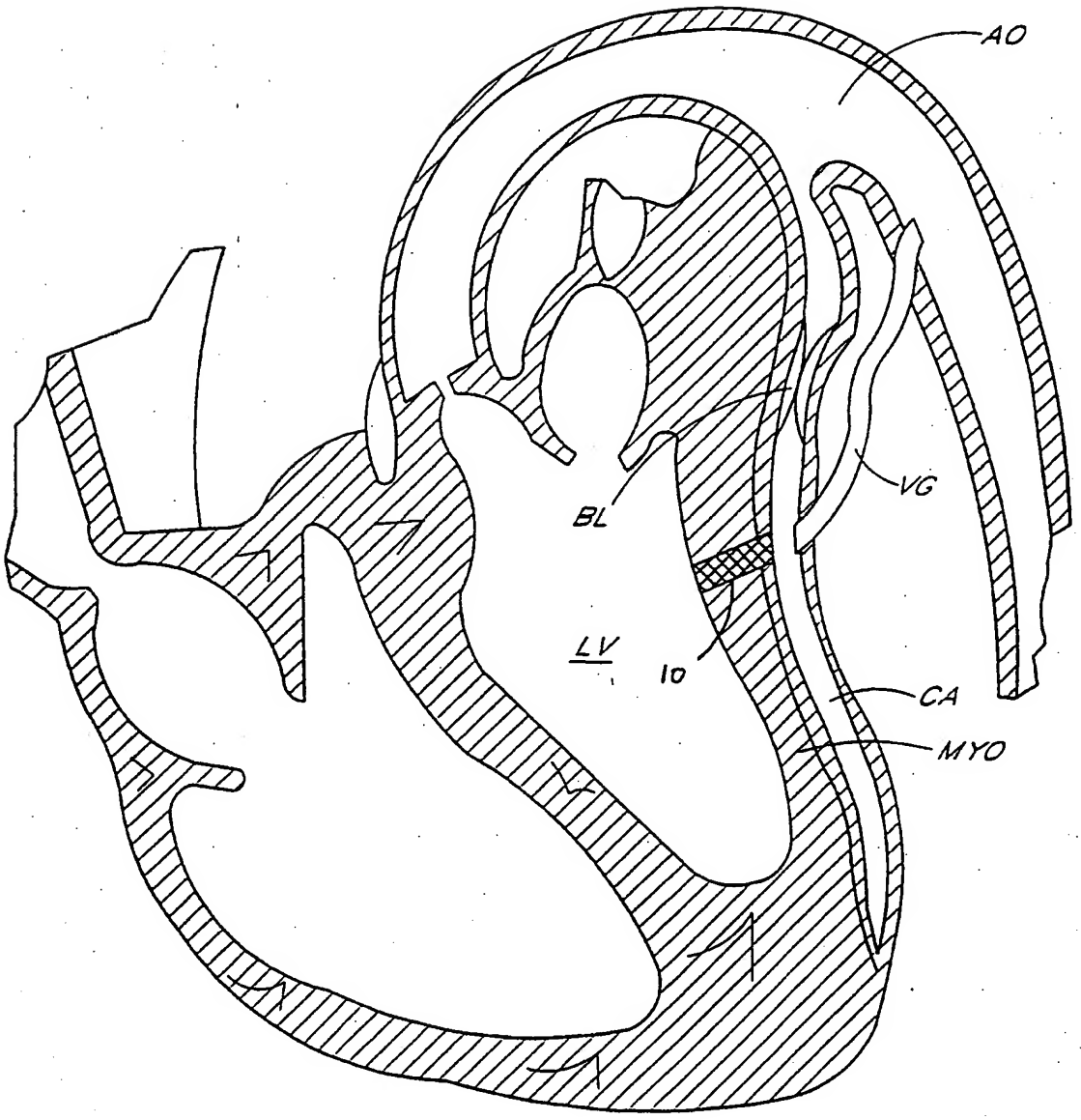



FIG. 2

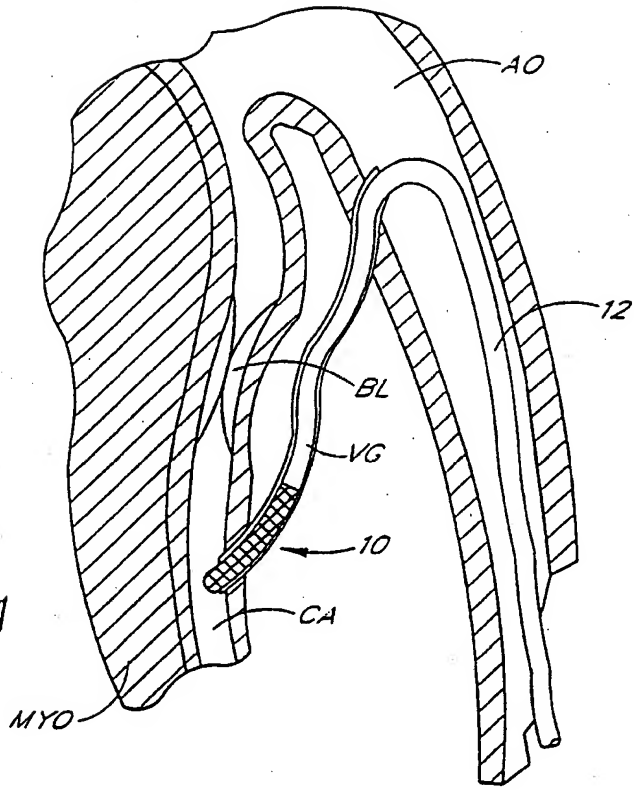



FIG. 3A

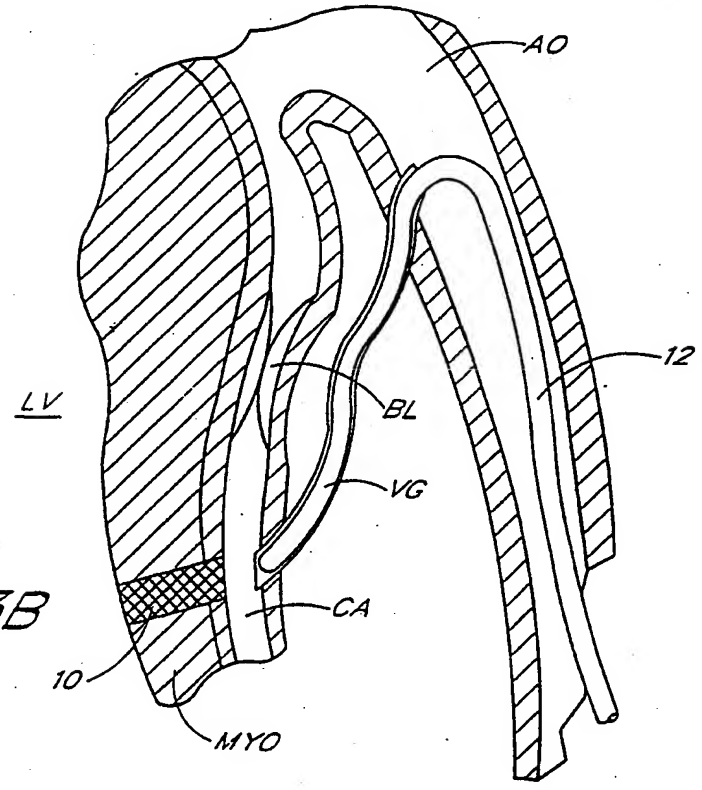



FIG. 3B

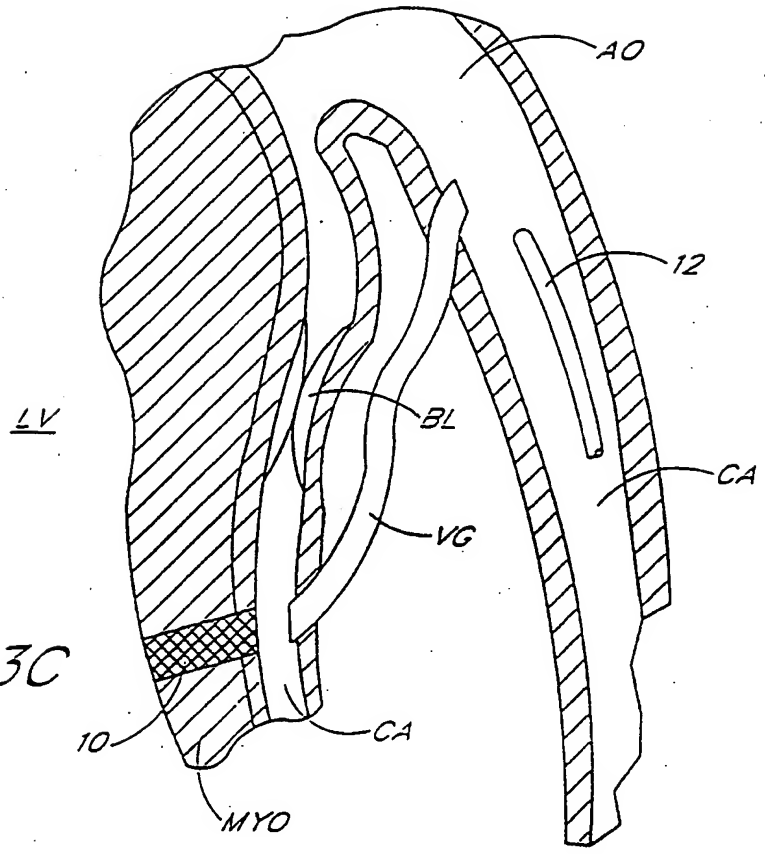



FIG. 3C

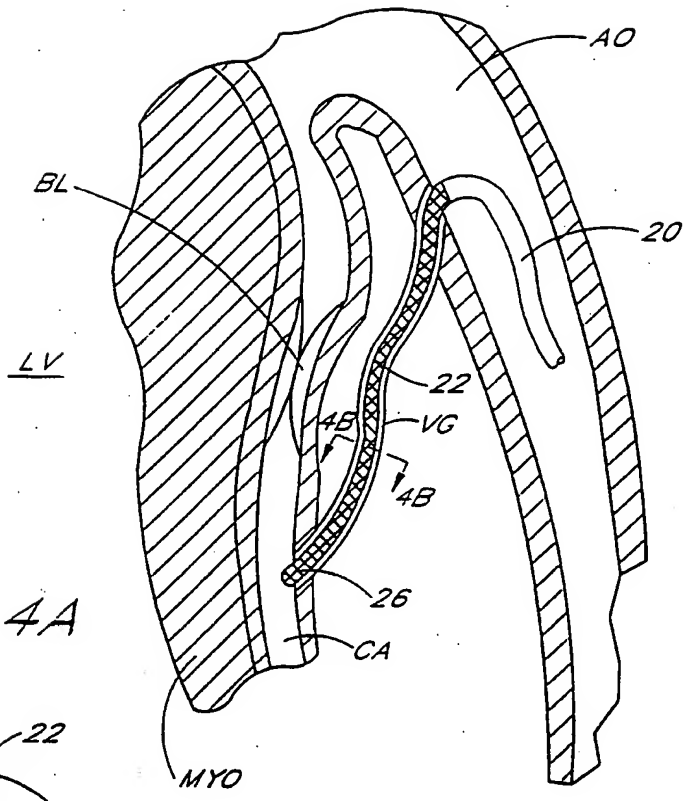



FIG. 4A

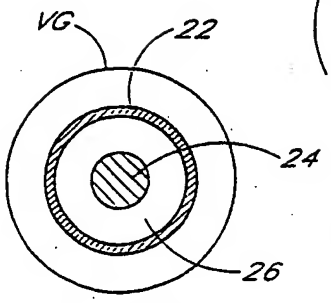



FIG. 4B

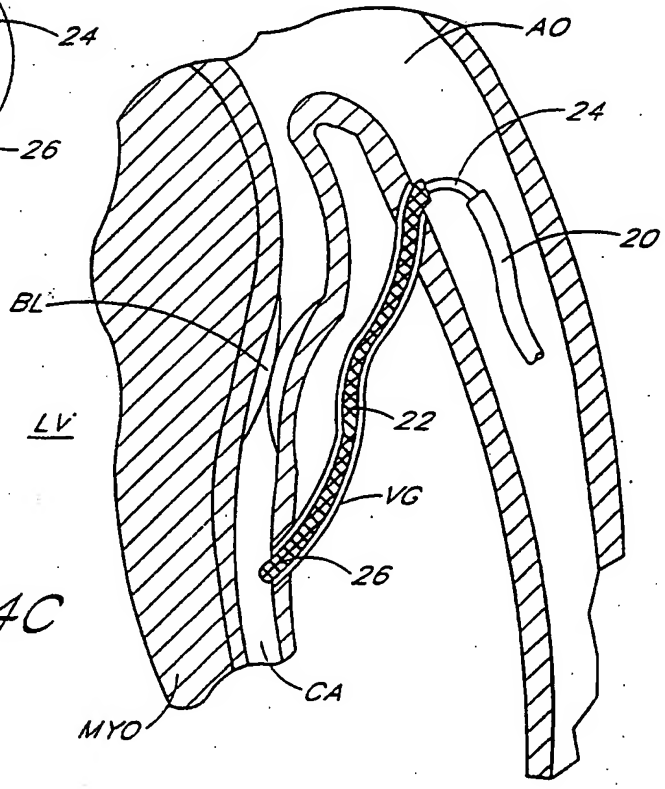



FIG. 4C

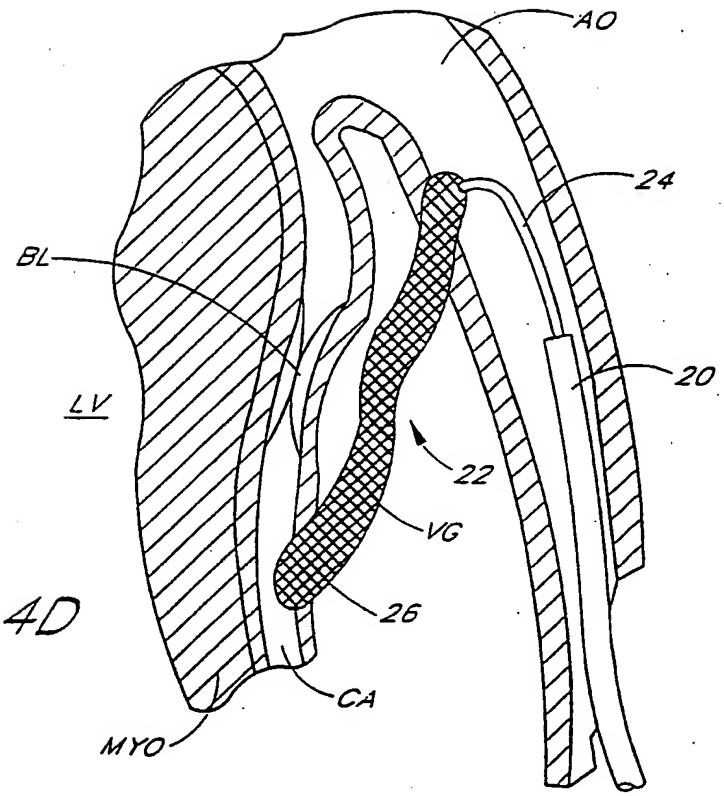



FIG. 4D

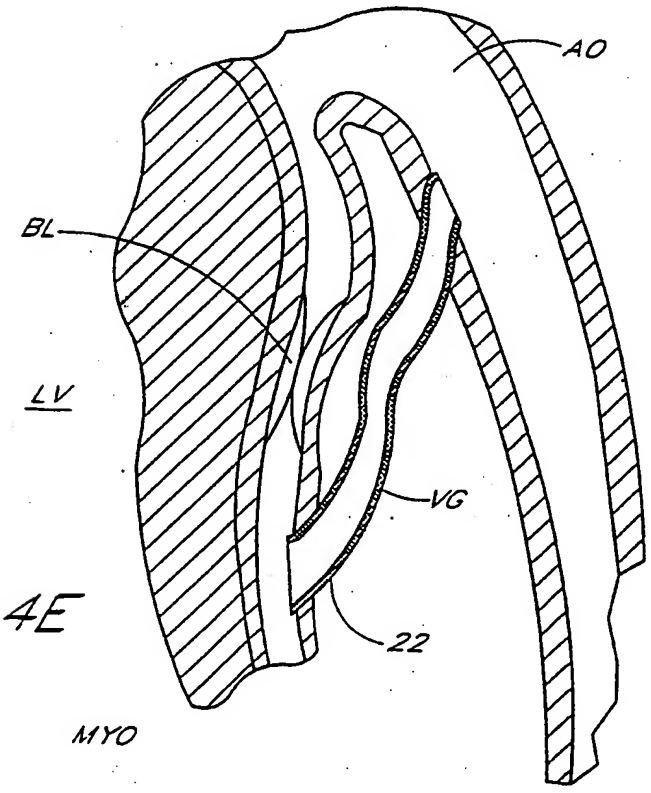



FIG. 4E

# INTERNATIONAL SEARCH REPORT

Internation pplication No
PCT/US 00/21121

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | US 5 931 842 A (GOLDSTEEN DAVID S ET AL)<br>3 August 1999 (1999-08-03)<br>column 4, line 33 -column 5, line 5;<br>figures 4-6 | 19-22,24 |
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| X | US 5 800 522 A (LEWIS JAMES D ET AL)<br>1 September 1998 (1998-09-01)<br>claim 1; figures; example 9 | 19 |

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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| Date of the actual completion of the international search | Date of mailing of the international search report |
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Info. ..tion on patent family members

Internation ..plication No
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